

**IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA**

BEST MEDICAL INTERNATIONAL, INC.,)	
Plaintiff,)	
)	
v.)	2:10-cv-1043
)	
ACCURAY, INC., a corporation,)	
)	
Defendant.)	

MEMORANDUM OPINION AND ORDER

Now pending before the Court are ACCURAY’S OBJECTIONS TO SPECIAL MASTER’S REPORT AND RECOMMENDATION (“R&R”) ON CLAIM CONSTRUCTION (Document No. 154). Plaintiff Best Medical International, Inc. (“BMI”) filed a brief in opposition to Accuray’s objections advocating that the Court adopt the R&R in its entirety. Accuray filed a reply brief and the Objections are ripe for disposition.

Factual and Procedural History

The full procedural history of this contentious patent infringement case has been set forth in the Court’s previous opinions¹ and need not be reiterated at length herein. Briefly summarized, BMI is the owner of United States Patent No. 6,038,283 (“the ‘283 Patent”) entitled “Planning Method and Apparatus for Radiation Dosimetry.” The patent involves “a method and apparatus for determining an optimized radiation beam arrangement for applying radiation to a tumor target volume while minimizing radiation of a structure volume in a patient” (in layman’s terms, planning cancer radiation treatment to maximize the dose delivered to a tumor while

¹ See Docket Nos. 33, 46, 54, 56, 62, 69, 87, 115, 126.

² BMI responds, convincingly, that Claim 29 is distinguishable because it is a “means plus function” claim.

³ As discussed above, Accuray would also read in a limitation to use of the SARP algorithm.

minimizing the damage to the surrounding healthy tissue). The technology is complex. Indeed, the "person of ordinary skill in the art" must have a masters degree or doctorate in radiation dosimetry, physics, medical physics, medicine, or an equivalent field of study; plus several years of clinical experience in radiation treatment planning.

The only legal issue remaining in this case is the contention of BMI that Accuray's new cancer treatment system, the CyberKnife VSI System, directly infringes claims 25 and 29 of its '283 Patent. The Court appointed attorney Gale R. "Pete" Peterson as Special Master to conduct the patent claim construction in this case, in light of the complex technical issues involved. After extensive development of the record and briefing by the parties (Document Nos. 131, 134, 135, 138, 139, 142, 146), the Special Master conducted a Claim Construction ("*Markman*") hearing on May 16, 2012. The Court was present for the entirety of the *Markman* hearing.

On September 7, 2012, the Special Master filed a 193-page Report and Recommendation ("R&R") on claim construction. The R&R contained extensive discussion of claim construction principles; the '283 Patent; the disputed claim terms; and the parties' respective positions and arguments thereto. With respect to Claim 25, the Special Master discussed the respective roles of the claims and specification, the actual text of the claims and specification, the prosecution history and the extrinsic evidence (notably, the Declaration of Dr. Isaac Rosen on behalf of Accuray). The Special Master has recommended that: (1) Claim 25 "is not limited to optimization by simulated annealing, or SARP," R&R at 101; (2) the term "Cost Function" is not limited to the cost function disclosed in column 13, lines 4-39, of the '283 Patent, R&R at 143; and (3) the term "Changing the beam weights" means "changing the beam intensity, including changing beam weights to zero or non-zero, but not including changing the number or position of beams." R&R at 157. The Special Master also recommended that the Court conclude that Claim

25 is not invalid as indefinite under 35 U.S.C. § 112 § 2. As to Claim 29, the Special Master recognized that the parties had agreed on all claim construction issues, and noted that Accuray's contention that claim 29 was indefinite would be the subject of a separate motion and briefing.

Discussion

Accuray has articulated numerous objections to the R&R, which the Court will review de novo pursuant to Fed. R. Civ. P. 53(f). Accuray contends that the Special Master has failed to construe all of the disputed claim terms sufficiently to resolve the parties' disputes and improperly narrowed the issues in dispute without the consent of the parties. More specifically, Accuray objects that the Special Master: (1) improperly construed claim 25 as not limited to the Simulated Annealing Optimization Algorithm ("SARP"); (2) did not state whether claim 25 was limited to any optimization algorithm and did not tie his construction to a particular claim term; (3) improperly construed the term "cost function" as not limited to the disclosure in column 13, lines 1-39; (4) did not construe the term "cost function" even though he admitted that the cost function is a modified cost function that uses cumulative dose volume histograms ("CDVH curves"); (5) improperly construed the term "changing the beam weights" to encompass "including changing beam weights to zero or non-zero"; and (6) failed to construe sixteen (16) other disputed terms for both claims 25 and 29. Accuray Brief at 2.

BMI has not filed any objections to the R&R and urges that it be adopted in its entirety.

A. Whether the Special Master Construed All Disputed Claim Terms

Accuray contends that the Special Master failed to construe all of the terms in dispute and improperly pressured Accuray to limit its presentation. The Court cannot agree.

As a procedural matter, Accuray was given a full opportunity to present its case. The Court was present throughout the proceeding and verifies that both parties had the right and opportunity to continue into a second day of hearing if either so chose. Although the Special Master did express his preference to conclude the claim construction hearing in one day, he also clearly emphasized that the next day had been reserved for additional evidence and/or argument and that he would be available for whatever time necessary as counsel preferred. *See* Hearing Transcript at 65:

MS. JELLINS: Could I ask one question, which I missed the discussion this morning before this procedure started, and I understand you wanted to cover as much as possible today, will we have time tomorrow morning to wrap up, if necessary?

MR. PETERSON: Yes. Actually, you have two days. I guess I was encouraging the parties this morning, since we're not going to take testimony, that because you have the time, you don't necessarily need to use it. You have it and you can use it, but there is nobody requiring you to use it. Yes, we would like to get in everything we can today. If we can finish today, that would be great. But if we can't, that's fine. We'll take whatever time is necessary tomorrow.

Accuray did not request additional time and did not mention anything additional that it wished to present or argue. Indeed, before concluding the hearing, the Special Master asked: "Is there anything else from the parties?" Counsel for Accuray replied: "Nothing from us, thank you." Hearing Transcript at 157. In sum, Accuray was neither pressured nor precluded from presenting all of its contentions and arguments. Accuray's complaints now are without basis or merit.

As a substantive matter, the Special Master resolved all of the disputed claims. Many of the disputed terms in claim 25 involved the same underlying issue – i.e., whether a limitation to

the SARP algorithm should be read into each claim term. The Special Master was well aware of each claim term that was disputed by the parties (*see* chart, R&R pp. 21-32). However, he perceived that it would be more efficient to handle many of these disputed claim terms in a group fashion. At the claim construction hearing, counsel for Accuray agreed with this methodology.

See Hearing Transcript at 136-37:

MR. PETERSON: Let me just ask you, as we're going through these, I see that you have broken these down; a computer means, and then computationally obtained. Bottom line, though, aren't you contending that all of these clauses mean a computer that is programmed to perform the SARP algorithm?

MS. JELLINS: Yes, perform -- yes, configured to and running the SARP algorithm to perform the function.

MR. PETERSON: So, really, the bottom line, instead of going through each one of these or construing each term, couldn't you simply say that this -- we contend that this phrase means a computer programmed to perform the SARP algorithm?

MS. JELLINS: Yes. . . .

MR. PETERSON: I don't want to put words in your mouth, but at the end of the day, your contention is these claims are limited to running the SARP algorithm, right?

MS. JELLINS: Yes.

MR. PETERSON: So can we make a distinction on the record that Accuray's contention is, on all of these, simply that your proposed construction is a computer program to perform the SARP algorithm?

MS. JELLINS: With respect to the language, the computer adapted to and further adapted to, yes. We believe that there are other terms, of course, that need to be construed but, yes, we agree. . . .

After further discussion between the Special Master and counsel for Accuray regarding the actual underlying disputes between the parties and what the Court was required to decide, the following exchange occurred at Transcript pp. 140-141:

MR. PETERSON: Wouldn't it be just easier to say what we want the Court to decide is whether or not Claim 25 is limited to the SARP algorithm, yes or no?

MS. JELLINS: That would be one thing that we would asking the Court to do. But I want to make clear that really, what -- again, talking about what is old and what is new, and the cost function is very important. So not only would we ask the Court to limit it to the simulated annealing algorithm, but we would also ask the Court to limit the cost function to the disclosed formulas in Column 13. If you want me to move to that to kind of shortcut things, I would be happy to do that.

MR. PETERSON: I don't really need to shortcut it. What I'm really trying to do is get at the core underlying dispute between the parties. If that core underlying dispute, the more and more read and hear, the core underlying dispute to me seems to be whether or not Claim 25 is limited to a computer program to perform the SARP algorithm. What I hear you saying is, yes, that's the core dispute, and if the Court decides that, everything else, other than the cost function, will fall into place.

Counsel for Accuray then explained that in her view, there were “three core disputes” regarding construction of Claim 25 of the '283 Patent that remained unresolved:

MS. JELLINS: Actually, there are three core disputes, as we have learned today. So if I can address those. One would be the SARP algorithm, you're absolutely correct. The second would be the cost function, can it be any cost function or is it the cost function disclosed in Column 13.

...

MS. JELLINS: And then the third question is, what does changing the beam weight mean? Does changing the beam weight mean changing the beam weight for the beam intensity, or does changing the beam weight also include changing the beam, like adding a beam or removing a beam?

See Hearing Transcript at 141-142.

The parties stipulated to the meaning of Claim 29 of the ‘283 Patent. The parties and Court further agreed that the issues regarding whether Claim 29 is “indefinite” and whether the ‘283 Patent is invalid would be the subject of separate motions and briefing.

The R&R addressed and construed all of the core disputed issues, as the Special Master and the Court understood them to be at the time of the hearing, and as those issues had been defined and framed by counsel for Accuray. Accuray’s instant attempt to disavow the position it took at the hearing is not persuasive. This objection is **DENIED**.

B. Whether Claim 25 Is Limited to the SARP Algorithm

Accuray acknowledges that the SARP algorithm is not specifically referenced in claim 25. Nevertheless, Accuray urges the Court to adopt a construction which would limit the scope of claim 25 (and each disputed term therein) to use of the SARP algorithm. Accuray reasons that a person skilled in the art would know that only a stochastic algorithm could perform the functions set forth in claim 25, and within the class of stochastic algorithms, SARP is the best-known and most commonly used. Accuray argues that the ‘283 Patent describes only a narrow improvement over the prior art by which a modified cost function, that uses partial volume data and CDVH curves to account for the tumor structure volumes as a whole and the relative importance of surrounding structures, is incorporated into the SARP algorithm. In other words, Accuray contends that while the ‘283 Patent may describe a new cost function, it does not describe a new optimization algorithm. Accuray also points out that BMI has agreed that Claim

29, which contains similar language regarding an optimized radiation beam arrangement, is limited to SARP.²

BMI concedes that SARP is the only optimization method disclosed in the Detailed Description of the Invention. However, BMI contends that Accuray is improperly attempting to limit the scope of the claim to its preferred embodiment, contrary to the principles set forth in *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (en banc). BMI maintains that it is improper to import a limitation from the described embodiment into the actual claims. *Id.* at 1323. BMI asks the Court to construe the disputed terms in claim 25 in accordance with their ordinary and customary meanings by applying the commonly accepted understanding of the words.

The Court agrees with BMI. A patentee is entitled to the full scope of its claims and cannot be limited to its preferred embodiment. *Id.* at 1323. In Column 8 lines 51-57 of the ‘283 Patent, the inventor specifically provided that the ‘283 Patent “is not intended to limit the invention to that embodiment.” To the contrary, the inventor intended to cover “all alternatives, modifications, and equivalents, as may be included within the scope and spirit of the invention.” *Id.* The patent, as a whole, reflects that this language is not mere boilerplate. The Background of the Invention referenced SARP as just “[o]ne such computational method.” Column 3, lines 21-22. Moreover, the inventor clearly knew how to specifically limit the scope of a claim to SARP, if that had been his intent, because claims 3, 5, 15, 19, 43 and 45 are so limited. By stark contrast, Claim 25 has no such textual limitation to SARP. In sum, the Special Master correctly concluded that Claim 25 (and each disputed term therein) is not limited to SARP and Accuray’s objection is not persuasive. This objection is **DENIED**.

² BMI responds, convincingly, that Claim 29 is distinguishable because it is a “means plus function” claim.

C. Cost Function

Accuray argues that the '283 Patent is limited to the "Cost Function" formula described in column 13, lines 4-39. Accuray also points to the parallel formula in the Summary of Invention, column 4, lines 40-66. In essence, Accuray contends that the inventor acted as its own lexicographer to explicitly define the term "cost function" to mean the specific formula set forth in columns 4 and 13.

Accuray reasons that the Court must focus on the state of the art, as described by Dr. Rosen, and "what the inventors invented." Accuray contends that the inventor discussed the disadvantages of the cost functions used in the prior art and then implicitly defined the term "cost function" by using it throughout the specification to refer to a "modified cost function" having very specific features, including CDVH curves divided into zones. Accuray contends that this modified cost function using CDVH curves is the only aspect of the claimed invention that was "new."

BMI contends that the term "cost function" is expressly defined at column 13, lines 1-4, and that the formula in lines 4-39 is not part of such definition. BMI contends that the formula merely describes the preferred embodiment, and therefore, should not be read as a limitation on the scope of claim 25.

The Court agrees with BMI. The '283 Patent, column 13, lines 1-4, defines the term "cost function" as follows:

The cost function is an analytical determination of whether, when any change is made to the strengths of the beams being used to treat the patient, the resultant dose distribution is closer to the result desired by the user.

The Court concludes that the inventor did act as his own lexicographer to describe a rather general term. Indeed, the term “cost function” was generally known in the art at the time and the inventor used the term in accordance with its ordinary meaning.

The Court acknowledges that there are several references in the ‘283 Patent to a cost function based on CDVH curves, or a cost function that is compatible with SARP. In column 13, lines 4-5, the inventor refers to the “cost function of the present invention” and then describes a formula for the assignment of relative weights to each zone of the CDVH curve to yield a total cost. In column 12, lines 34-38, the ‘283 Patent states that except for the “cost function utilized in the present system,” the details of SARP are known in the art. In column 15, lines 41-46, the ‘283 Patent states that the “cost function of the present invention” may be easily incorporated into SARP algorithms.

On the other hand, nowhere in claim 25 did the inventor limit the “cost function” to a specific formula. Claim 25 simply requires “a cost function.” (Emphasis added). It does not require “the” specific cost function formula described in column 13, lines 4-39. Similarly, in column 4 line 33, the inventor states that “the cost function may be obtained” by way of the CDVH formula. (Emphasis added). In claims 1, 14, 18 and 40, the inventor explicitly referenced CDVH curves. There is no such limiting reference in claim 25. Even more clearly, dependent claim 26 references the “apparatus of claim 25, wherein the partial volume data is represented as a CDVH.” Column 20, lines 25-26. *See also* Claim 28 (dependent claim explicitly citing use of CDVH). The inventor must have intended that Claim 25 not be limited to a formula based on CDVH curves, because such a limitation would render Claims 26 and 28 superfluous. The Special Master correctly concluded that the term “cost function” is defined at column 13, lines 1-4 in accordance with its ordinary meaning and does not mandate the use of

the formula described in columns 4 and 13 to the exclusion of all other possible optimization formulas. Accordingly, this objection to the R&R is **DENIED**.

D. Changing the Beam Weights

The final of the core disputed terms in claim 25 is “changing the beam weights.”

Accuray contended that “beam weights” should be construed to mean “beam intensities” such that changing the beam weights would mean “adding or subtracting small quanta of positive and negative beam intensities to the beam elements”³ BMI initially contended that the term “beam weights” means beam intensities or dose, which it asserted are synonymous. At the hearing, BMI retreated from its argument that “dose” is a synonym; and the Special Master agreed with Accuray that beam weights does not mean “dose.” Neither party has filed an objection to this aspect of the R&R.

However, the parties continue to dispute whether the term was limited to changing the intensities of existing beams, or also included adding or subtracting entire beams. Accuray contends that the addition/subtraction of entire beams is not within the term “changing the beam weights” because entire beams have not just intensity, but also geometry (i.e., orientation and direction). Accuray further argues that the Special Master and BMI have confused “beams” with “beamlets.” BMI contends that claim 25 should encompass both beam intensities/weights and also beam geometry/positions.

The Special Master’s proposed construction is a middle ground. He agreed with Accuray that claim 25 did not encompass all changes to beam geometry or positions. On the other hand, he agreed with BMI that changes to beam intensity could include changing a beam weight to

³ As discussed above, Accuray would also read in a limitation to use of the SARP algorithm.

zero or non-zero, but not including changing the number or position of beams. Accuray objects to this aspect of the R&R.

The Court agrees with the Special Master's proposed construction. As an initial matter, column 9, lines 29-34 of the Patent distinguishes the concepts of "beam arrangement" (i.e., the positions around the treatment field)⁴ and "beam weight" (i.e., beam intensity). In the prior art, Webb described optimization by changing beam intensities, but not by changing beam positions. *See, e.g.*, R&R at 156 (if the user started with 32 equispaced beams and then ran the SARP algorithm, the beam weights may change but the number and position of the beams would remain the same – 32 equispaced beams). The Court concludes that setting a beam intensity at any given position to zero, or alternatively, changing a particular beam intensity from a default setting of zero to some greater intensity, constitutes "beam weight" rather than "beam arrangement." Thus, setting a particular beam to zero, or non-zero, constitutes a change in beam weight. Accordingly, this objection to the R&R is **DENIED**.

Conclusion

The Special Master performed an exhaustive analysis of the applicable law and the contentions of the parties. The Special Master resolved the "three core disputes," as he and the Court understood them to be, and as they had been iterated by counsel for Accuray. The Court has conducted a de novo review and has independently determined conclusions on the issues in dispute. Accuray's objections are **DENIED** and the Special Master's R&R is adopted as the opinion of the Court.

⁴ Figure 1 of the Patent depicts a linear accelerator, including a rotatable couch, collimator and gantry, by which beams of radiation may be delivered at different angles.

The purpose of the *Markman* hearing was to construe disputed claim terms. The Court recognizes that there will likely be further litigation with regard to the issues of indefiniteness and/or invalidity, and infringement. Under the circumstances as developed at the hearing, the Court does not agree with Accuray's contention that the Special Master failed to construe all of the disputed claim terms. To the contrary, all of the core disputed issues were addressed and construed: Claim 25 is not limited to the SARP algorithm; the term "cost function" is defined at column 13, lines 1-4 of the Patent; and the term "changing the beam weights" means changing the beam intensity, including setting the intensity to zero or non-zero, but does not include changes to beam arrangement or positioning. The parties did not preserve any disputes regarding the construction of Claim 29.

An appropriate Order follows.

McVerry, J.

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BEST MEDICAL INTERNATIONAL, INC.,)	
Plaintiff,)	
)	
v.)	2:10-cv-1043
)	
ACCURAY, INC., a corporation,)	
)	
Defendant.)	

ORDER OF COURT

AND NOW, this 11th day of January, 2013, in accordance with the foregoing Memorandum Opinion, it is hereby ORDERED, ADJUDGED and DECREED that ACCURAY'S OBJECTIONS TO SPECIAL MASTER'S REPORT AND RECOMMENDATION ("R&R") ON CLAIM CONSTRUCTION (Document No. 154) are **DENIED**. The Report and Recommendation of the Special Master filed on September 7, 2012 is adopted as the opinion of the Court.

BY THE COURT:

s/Terrence F. McVerry
United States District Judge

cc: Special Master
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